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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,992	04/17/2001	Yuichi Obata	L0461/7112 (JRV/MXA)	6680

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EXAMINER	
HOLLERAN, ANNE L 16	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 03/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/835,992	OBATA, YUICHI	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *1-12 and 16-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-15,31 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election with traverse of Group I, claims 13-17 (in part), 31 and 32 (in part) in Paper No. 9, filed Nov. 19, 2002, is acknowledged. The traversal is on the ground(s) that there would not be a serious burden on the examiner to examine both groups, because both groups are drawn to methods for assay of antibodies and the antibodies bind to antigens that are related in that they are both discovered in serological testing of gastric cancer patients, and appear to share common epitopes. This is not found persuasive because, the antigens are separate and distinct polypeptides that are unrelated to each other, and require different searches in the non-Patent literature and in the sequence databases. Applicant has failed to point out any specific errors in the restriction requirement, and supplied no evidence on the record that the two antigens are structurally related.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 13-15 (to the extent the claims are drawn to methods for detecting antibodies that bind to sterol carrier protein-x/sterol carrier protein-2), 31 and 32 (to the extent the claims are drawn to methods for detecting antibodies that bind to sterol carrier protein-x/sterol carrier protein-2) are examined on the merits.

Claims 1-32 are pending.

Claims 1-12, and 16-30, drawn to non-elected inventions, are withdrawn from consideration.

Information Disclosure Statement

3. Reference C12 was not considered, because it was not found with parent file 08/896,164.

Claim Objections

4. Claim 13 is objected to because of the following informalities: claim 13 appears to be drawn to a method for determining gastric cancer in a sample. Because samples do not have diseases, clam 13 appears to be grammatically incorrect. Appropriate correction is required.

5. Claims 13-15, 31 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13 and 31 are indefinite, because they recite "related condition", where the condition is "related" to gastric cancer. The specification contains no definition of what conditions are within the scope of the term "related condition". Therefore, the scope of the claim is unclear.

6. Claims 13-15, and 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The basis for this rejection is that the specification lacks a written description of the genus of conditions that are to be determined by the operation of the claimed method.

The specification teaches that use of the SEREX method resulted in the detection of SEQ ID NOS: 19, 20, 21 and 22 in tumor cells of patients diagnosed with gastric cancer. The claims are drawn to methods comprising the detection of antibodies that bind to proteins encoded by any of SEQ ID NOS: 19, 20, 21, or 22, where the methods are drawn to methods for the detection of gastric cancer or related conditions, or the methods are drawn to methods for following progress of a therapeutic regime designed to alleviate gastric cancer or a related condition. Therefore, the claims are drawn to methods for detection of, or following the progress of a genus of conditions. The specification fails to describe any other conditions that may be associated with detection of antibodies that bind to the protein products of SEQ ID NOS: 19, 20, 21 and 22. The specification fails to provide a definition of what constitutes a condition that is "related" to gastric cancer. Therefore, the specification fails to describe the genus of conditions to be detected or monitored by the claimed methods, applicant does not appear to have been in possession of the claimed methods at the time the application was filed.

7. Claims 13-15, 31 and 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation would be required to practice the full scope of the claimed inventions are: 1) quantity of experimentation necessary; 2) the amount of direction or guidance presented in the specification; 3) the presence or absence of working examples; 4) the nature of the invention; 5) the state of the prior art; 6) the

relative skill of those in the art; 7) the predictability or unpredictability of the art; and 8) the breadth of the claims. See Ex parte Forman, 230 USPQ 546, BPAI, 1986.

Claims 13-15, 31 and 32 are rejected for lack of enablement, because the specification fails to teach that the detection of antibodies that specifically binds sterol carrier protein-X/sterol carrier protein-2, or of antibodies that bind to proteins encoded by any of SEQ ID Nos: 19, 20, 21 and 22, can be used to determine gastric cancer or to monitor the progress of a gastric cancer patient. The specification also fails to provide any teachings that the presence of such antibodies in the sera of individuals is associated with any other disease, and therefore, fails to show that the presence of such antibodies are diagnostic of any disease or can be used in methods to monitor the progress of any disease.

The specification teaches that the SEREX method was used to find novel cancer antigens in gastric cancer patients. Sera from patients having gastric cancer were used to screen clones derived from cDNA libraries. The specification teaches that among the sequences identified were the nucleotide sequences of SEQ ID NOS: 19, 20, 21 and 22, which appear to be part of the coding sequence of sterol carrier protein-X/sterol carrier protein-2. Thus, the experiments described in the specification demonstrate that some gastric cancer patients possess antibodies that bind to sterol carrier protein-X/sterol carrier protein-2, but the specification fails to demonstrate that the existence of these antibodies is specific to gastric cancer patients or any other type of cancer or disease.

The SEREX method is used to identify potential cancer antigens, but further experimental work must be done to establish that proteins or nucleic acids, or the antibodies that bind to the proteins are useful in methods of diagnosis or disease monitoring. Zhang (Zhang, H.

et al. Zhongguo Mianyixue Zazhi 18(2): 98-101, 2002; Abstract only) teaches that the SEREX method was used to identify ovarian cancer antigens, MY-OVA-2, 7 and 13. However, when the purified proteins were used to test the seroreactivity of patients and healthy controls, only 1 out of the three putative antigens was found in tumor patients and not the normal controls.

Sterol carrier protein-X/sterol carrier protein-2 has been sequenced, and the human sequence is taught by Ohba (Ohba, T. et al., Genomics 24(2): 370-374, 1994; see NCBI record, accession no. I38205). The prior art does not teach or suggest that sterol carrier protein-X/sterol carrier protein-2 is abberantly expressed, mutated or overexpressed in any type of cancer, or in any other disease.

In view of the failure of the specification to establish that the existence of sterol carrier protein-X/sterol carrier protein-2 antibodies is diagnostic for gastric cancer, or any other disease, and in view of the teachings of Zhang that SEREX-identified antigens are not always useful for screening patients for cancer, it appears that it is unpredictable that methods comprising the detection of antibodies that bind to sterol carrier protein-x/sterol carrier protein-2 could be used to diagnose gastric cancer, monitor gastric cancer, or diagnose or monitor any other disease. Thus, the specification appears to present nothing more than an invitation to experiment for the purpose of discovering an association, if any exists, between antibodies to sterol carrier protein-x/sterol carrier protein-2 and any disease.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

ALH

Anne L. Holleran
Patent Examiner
March 9, 2003

CA

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